REMARKS

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

(1) Claim Amendments

Claims 16-21 and 23 were pending in this application when examined.

Claims 16-21 and 23 have been cancelled, and new claim 24-37 have been added.

Claim 24 corresponds with cancelled claim 16 but further recites "a sugar" in a first chamber, and "an amino acid" in a second chamber. Support for claim 24 can be found on page 8, lines 25-27, page 11, lines 7-9, Tables 2 and 3 and pages 24-25 (Example 2) of the specification.

Support for claim 25 can be found on page 10, lines 11-17 of the specification.

Support for claim 26 can be found on page 10, lines 15 and 16 of the specification.

Support for claim 27 can be found on page 11, lines 9-14 of the specification.

Claim 28 corresponds with cancelled claim 17, and support for claim 28 can be found on page 8, lines 22-27 of the specification.

Claim 29 corresponds with cancelled claim 23, and support for claim 29 can be found in Example 1 in Table 1 of the specification.

Claim 30 corresponds with cancelled claim 18.

Claim 31 corresponds with cancelled claims 19-20, and support for claim 31 can be found on page 8, lines 25-27 and page 10, lines 26-28 of the specification.

Support for claim 32 can be found on page 9, lines 6-11 of the specification.

Support for claim 33 can be found on page 9, line 9 of the specification.

Support for claim 34 can be found on page 10, lines 28-29 of the specification.

Support for claims 35 and 36 can be found on page 8, lines 25-27 of the specification.

Claim 37 corresponds with cancelled claim 21.

(2) Claim Rejection Under 35 U.S.C. § 103 over Segers et al. in view of Nakamura et al.

The Examiner rejects claims 16-23 under 35 U.S.C. 103 (a) as being unpatentable over Segers et al. (US 5,383,324) ("Segers") in view of Nakamura et al. (US 6,867,193) ("Nakamura"). As applied to the new claims, Applicants respectfully traverse the rejection.

(2-1) Claims 24 to 30

(2-1-a) The Features of Claim 24

Claim 24 recites the following features:

(i) a first solution containing a potassium salt and a sugar in a first chamber;

(ii) a second solution containing a potassium salt and an amino acid in a second chamber;

(iii) the first solution and the second solution each have the same potassium salt; and

(iv) the first solution and the second solution **each have a potassium ion concentration of about 13 to 35 mEq/L**.

(2-1-b) Segers

Segers discloses in column 7, lines 42 -50 that "when the solution contained in the upper chamber 44 is mixed with the solution contained in the lower chamber 46, the subsequent peritoneal dialysis solution has the following composition:…0.0 to about 3.0 (mmol/L) potassium" (emphasis added).

However, the reference does not disclose or suggest a solution having "a potassium ion concentration of about **13 to 35 mEq/L**", feature (iv) of claim 24, the reference provides no reason or motivation to those of ordinary skill in the art to prepare an aseptic combination preparation with a potassium ion concentration of about "13 to 35 mEq/L".

In the Advisory Action, the Examiner asserts that a *prima facie* case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties (see page 2, lines 20-22) (MPEP 2144.05).

However, the recited potassium concentration range of "about 13 to 35 mEq/L" is clearly outside of the range of "0.0 to about 3.0 mmol/L", which is disclosed in Segers. Thus, the recited range is very different and **not at all close** to the range disclosed in the reference such that one of ordinary skill in the art would not expect them to have similar properties. Thus, a *prima facie* case of obviousness cannot be established under MPEP 2144.05.

Therefore, those skilled in the art would not have arrived at feature (iv) of claim 24 from Segers.

(2-1-c) Nakamura

Nakamura does not disclose or suggest a potassium ion concentration at all. Thus, the reference does not disclose or suggest feature (iv) of claim 24. Therefore, Nakamura does not cure the deficiency of Segers.

In the Advisory Action, the Examiner asserts that one cannot attack references individually where the rejections are based upon a combination of references (see page 2, lines 26-29).

However, as discussed above, the references alone, or in combination, do not teach each and every feature of claim 24.

(2-1-d) Unobviousness of Claims 24-30

For the foregoing reasons, those skilled in the art would not have arrived at feature (iv) of claim 24, as well as the specific combination of feature (iv) with features (i) - (iii) of claim 24, from Segers in view of Nakamura.

Therefore, claim 24 would not have been obvious over Segers in view of Nakamura.

Claims 25-30 depend directly from claim 24, and thus also would not have been obvious over the references.

(2-2) Claims 31 to 37

(2-2-a) The Features of Claim 31

Claim 31 recites the following features:

(i) a first solution containing a sodium salt and a sugar in a first chamber;

(ii) a second solution containing a sodium salt and a bicarbonate salt in a second chamber;

(iii) the first solution and the second solution each have the same sodium salt; and

(iv) the first solution and the second solution **each have an osmotic pressure ratio of about 1 relative to physiological saline**.

(2-2-b) Segers

Segers does not disclose or suggest osmotic pressure ratio at all. Thus, those skilled in the art would not have arrived at "**an osmotic pressure of about 1 relative to physiological saline**", feature (iv) of claim 31, from the reference.

(2-2-c) Nakamura

Nakamura discloses in column 5, lines 11-13 and 52-53 and column 6, lines 27-29 a solution having an osmotic pressure ratio of **2.8 to 3.3**.

Nakamura does not disclose or suggest a solution having "**an osmotic pressure of about 1 relative to physiological saline**", feature (iv) of claim 31. Furthermore, one of ordinary skill in the art would have had no reason or motivation to prepare an aseptic combination preparation with an osmotic pressure ratio of about 1 relative to physiological saline in view of the reference.

In addition, the recited osmotic pressure ratio of **about 1** is clearly distinct from "2.8 to 3.3", as disclosed in the reference, such that one of ordinary skill in the art would not expect them to have similar properties. Thus, a *prima facie* case of obviousness cannot be established under MPEP 2144.05.

Accordingly, Nakamura does not disclose or suggest feature (iv) of claim 31. Therefore, Nakamura does not cure the deficiency of Segers.

(2-2-d) Unobviousness of Claims 31-37

For the foregoing reasons, those skilled in the art would not have arrived at feature (iv) of claim 31, as well as the specific combination of feature (iv) with features (i) - (iii) of claim 31, from Segers in view of Nakamura.

Therefore, claim 31 would not have been obvious over Segers in view of Nakamura, each reference taken alone **or in combination**.

Claims 32-37 depend directly from claim 31, and thus also would not have been obvious by the references.

(3) Claim Rejection Under 35 U.S.C. § 103 over Veech in view of Nakamura

The Examiner rejects claims 16-23 under 35 U.S.C. 103(a) as being unpatentable over Veech (US 5,200,200) in view of Nakamura. As applied to the new claims, Applicants respectfully traverse the rejection.

(3-1) Claims 24-30

As discussed above, claim 24 recites the following features:

(i) a first solution containing a potassium salt and a sugar in a first chamber;

(ii) a second solution containing a potassium salt and an amino acid in a second chamber;

(iii) the first solution and the second solution each have the same potassium salt; and

(iv) the first solution and the second solution **each have a potassium ion concentration of about 13 to 35 mEq/L**.

(3-1-a) Veech

Veech discloses a solution containing 0-5 mM/liter of K+ (potassium ion) (see column 6, lines 11-39). However, the reference does not disclose or suggest "**a second solution containing a potassium salt and an amino acid in a second chamber**", feature (ii) of claim 24.

In addition, Veech does not teach or suggest a solution having a potassium ion concentration of "**about 13 to 35 mEq/L**", feature (iv) of claim 24, and one of ordinary skill in the art would have had no reason or motivation to prepare an aseptic combination preparation with a potassium ion concentration of about 13 to 35 mEq/L in view of the reference.

Furthermore, the recited potassium ion concentration of about **13 to 35 mEq/L** is clearly outside the range of "0-5 mM/liter" disclosed in the reference such that one of ordinary skill in the art would not expect them to have similar properties. Thus, a *prima facie* case of obviousness cannot be established under MPEP 2144.05.

Therefore, those skilled in the art would not have arrived at features (ii) and (iv) of claim 24 from Veech.

(3-1-b) Nakamura

Nakamura also does not tech or suggest the specific combination of a potassium salt and an amino acid (feature (ii)), and a potassium ion concentration of about 13 to 35 mEq/L (feature (iv)) of claim 24. Therefore, Nakamura does not cure the deficiencies of Veech.

(3-1-c) Unobviousness of Claims 24-30

For the foregoing reasons, those skilled in the art would not have arrived at features (ii) and (iv) of claim 24, as well as the specific combination of features (ii) and (iv) with features (i) and (iii) of claim 24, from Veech in view of Nakamura.

Therefore, claim 24 would not have been obvious over Veech in view of Nakamura, each reference taken alone or in combination.

Claims 25-30 depend directly from claim 24, and thus also would not have been obvious over the references.

(3-2) Claims 31 to 37

As discussed above, claim 31 recites the following features:

(i) a first solution containing a sodium salt and a sugar in a first chamber;

(ii) a second solution containing a sodium salt **and a bicarbonate salt in a second chamber**;

(iii) the first solution and the second solution each have the same sodium salt; and

(iv) the first solution and the second solution each have an osmotic pressure ratio of about 1 relative to physiological saline.

(3-2-a) Veech

Veech discloses in column 6, lines 26-39, a solution containing HCO_3^- (a bicarbonate ion) and glucose (sugar). Thus, Veech's solution contains a bicarbonate ion and a sugar **together**.

However, claim 31 recites (i) "a first solution containing at least a sodium salt and **a sugar** in a **first chamber**" and (ii) "a second solution containing a sodium salt and **a bicarbonate salt** in a **second chamber**". Accordingly, the preparation of claim 31 includes a sugar and a sodium salt in first chamber, and a sodium salt and a bicarbonate salt in a second chamber, but does not include a bicarbonate salt and a sugar in the same chamber, as disclosed in the reference. Therefore, Veech does not disclose or suggest features (i) and (ii) of claim 31.

In addition, Veech does not disclose or suggest an osmotic pressure ratio at all. Therefore, Veech does not disclose feature (iv) of claim 31: "the first solution and the second solution each have an osmotic pressure ratio of about 1 relative to physiological saline".

Therefore, those skilled in the art would not have arrived at features (i), (ii) and (iv) of claim 31 from the reference.

(3-2-b) Nakamura

Nakamura does not disclose or suggest a bicarbonate salt, or the specific combination of a sodium salt and sugar in a first chamber. Accordingly, the reference does not disclose or suggest features (i) and (ii) of claim 31.

Further, as mentioned in item (2-2-c) above, the reference also does not disclose or suggest a solution having an osmotic pressure ratio of about 1 relative to physiological saline, feature (iv) of claim 31, and one of ordinary skill in the art would have had no reason or motivation to prepare an aseptic combination preparation with an osmotic pressure ratio of about

1 relative to physiological saline in view of the reference.

Moreover, as discussed above, the recited osmotic pressure ratio of about 1 is clearly distinct from "2.8 to 3.3" such that one of ordinary skill in the art would not expect them to have similar properties.

Accordingly, Nakamura does not disclose or suggest features (i) (ii) and (iv) of claim 31, and thus does not cure the deficiencies of Veech.

(3-2-c) Unobviousness of Claims 31-37

For the foregoing reasons, those skilled in the art would not have arrived at features (i), (ii) and (iv) of claim 31, as well as the specific combination of features (i), (ii) and (iv) with feature (iii) of claim 31, from Veech in view of Nakamura.

Therefore, claim 31 would not have been obvious over the references.

Claim 32-37 depend directly from claim 31, and thus also would not have been obvious over the references.

(4) Conclusion

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the applied references.

Therefore, in view of the foregoing amendments and remarks, it is submitted that the rejections set forth by the Examiner have been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

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